IN THE CIRCUIT COURT FOR DAVIDSON COUNTY, TENNESSEE TWENTIETH JUDICIAL DISTRICT AT NASHVILLE 2008 GCT -7 AM 9: 28

| | | richard R. Rocker. Clerk |
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| STATE OF TENNESSEE, ex rel. |) | Richard |
| ROBERT E. COOPER, JR., |) | Blall w |
| ATTORNEY GENERAL and |) | |
| REPORTER, |) | |
| |) | |
| Plaintiff, |) | |
| |) | . N |
| v. |) | Case No. |
| ************************************** |) | |
| ELI LILLY & CO., an Indiana |) | |
| corporation, |) | |
| |) | |
| Defendant. |) | |
| |) | |
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COMPLAINT FOR INJUNCTIVE AND OTHER RELIEF

1. This civil law enforcement action is brought in the name of the State of Tennessee ("State"), by and through Robert E. Cooper, Jr., the Attorney General and Reporter ("Attorney General"), pursuant to Tenn. Code Ann. §§ 8-6-109, 47-18-108, and 47-18-114, and all common law powers and duties of the Attorney General. Mary Clement, Director of the Division of Consumer Affairs of the Tennessee Department of Commerce and Insurance ("Division"), having reason to believe that Eli Lilly ("Lilly" or "Defendant"), an Indiana corporation, has violated and/or is continuing to violate the Tennessee Consumer Protection Act of 1977, Tenn. Code Ann. § 47-18-101 *et seq.*, has requested that this civil action against Defendant be commenced by the Attorney General. The Attorney General brings this action in the public interest.

JURISDICTION AND VENUE

- 2. This action is brought for and on behalf of the Division of Consumer Affairs of the Department of Commerce and Insurance by Robert E. Cooper, Jr., the Tennessee Attorney General and Reporter, pursuant to the Tennessee Consumer Protection Act of 1977, Tenn. Code Ann. § 47-18-101 *et seq*. This Court exercises jurisdiction over the subject matter of this Complaint pursuant to the provisions of Tenn. Code Ann. §§ 47-18-108 and 47-18-114.
- 3. Venue is proper in Davidson County pursuant to Tenn. Code Ann. § 47-18-108(a)(3) because it is a county in which Defendant conducts or has conducted business at all times relevant to this Complaint.
- 4. Defendant waived ten (10) days notice of intent to sue under Tenn. Code Ann. § 47-18-108(a)(2).

PARTIES

- 5. Plaintiff, State of Tennessee ex rel. Robert E. Cooper, Jr., is the duly appointed Attorney General of Tennessee and, as such, has broad statutory and common law powers. The Attorney General is authorized to enforce the Tennessee Consumer Protection Act of 1977 ("Act"), Tenn. Code Ann. § 47-18-101 *et seq.* Pursuant to Tenn. Code Ann. § 47-18-108, relief available includes, but is not limited to, injunctive relief, attorneys' fees, and civil penalties.
- 6. Defendant Eli Lilly and Company ("Lilly" or "Defendant") is an Indiana corporation that conducts business nationwide, including in the State of Tennessee; its principal place of business is Lilly Corporate Center, Indianapolis, Indiana 46285. Eli Lilly, at all times relevant hereto, engaged in trade and commerce affecting consumers, within the meaning of the Tennessee Consumer Protection Act of 1977 ("Act"), Tenn. Code Ann. § 47-18-101 et seq., in the State of Tennessee, including, but not limited to, Davidson County.

BACKGROUND

- 7. Zyprexa belongs to a class of drugs traditionally used to treat schizophrenia and commonly referred to as "atypical antipsychotics." When these drugs were first introduced to the market in the 1990s, it was hypothesized that they might be used as long-term treatment for schizophrenia without posing the same risks as first-generation antipsychotics. More specifically, experts thought that atypical antipsychotics would be less likely to produce extrapyramidal symptoms ("EPS") and tardive dyskinesia ("TD").
- 8. While these drugs may reduce the risk of EPS and TD associated with first-generation antipsychotics, they also produce dangerous side effects, including weight gain, hyperglycemia, diabetes, cardiovascular complications, and other severe conditions. Zyprexa has been shown to pose a high risk of weight gain, hyperglycemia, and diabetes.

DEFENDANT'S COURSE OF CONDUCT

Upon information and belief, the State alleges:

- 9. Lilly began marketing Zyprexa to health care professionals for the treatment of schizophrenia in 1996. Since then, the Food and Drug Administration ("FDA") has approved Zyprexa for the treatment of acute mixed or manic episodes of bipolar I disorder and for maintenance treatment in bipolar disorder.
- 10. Lilly engaged in an aggressive marketing campaign called "Viva Zyprexa!" As part of that campaign, the company marketed Zyprexa for a number of uses for which it was not approved by the FDA. For example, Lilly marketed Zyprexa for pediatric use, for use at high dosage levels, for the treatment of symptoms rather than diagnosed conditions, and for the treatment and/or chemical restraint of patients suffering from dementia.

11. Through this Viva Zyprexa! campaign, and all of the company's efforts to promote Zyprexa for uses for which it was not approved by the FDA, Lilly misrepresented the drug's approved uses, its safety, and its effectiveness.

VIOLATIONS OF LAW

- 12. The allegations contained in paragraphs 1-11 are incorporated herein by reference.
- 13. The Defendant, in the course of advertising, soliciting, selling, promoting and distributing the prescription drug Zyprexa, has engaged in a course of trade or commerce which constitutes unfair or deceptive acts or practices, and is therefore unlawful under the Tennessee Consumer Protection Act of 1977, Tenn. Code Ann. § 47-18-101 *et seq.*, particularly Tenn. Code Ann. § 47-18-104(a),(b)(5), and (b)(27) by misrepresenting that Zyprexa had characteristics, uses, benefits, and qualities that it does not have.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff, State of Tennessee, *ex rel.* Robert E. Cooper, Jr., Attorney General and Reporter, pursuant to the Act, the Attorney General's general statutory authority, the Attorney General's authority at common law and this Court's equitable powers, prays:

- A. That this Complaint be filed without cost bond as provided by Tenn. Code Ann. §§ 20-13-101, 47-18-108 and 47-18-116 and no court costs or litigation fees or costs of any sort be taxed against the State pursuant to Tenn. Code Ann. § 47-18-116;
- B. That process issue and be served upon Defendant requiring Defendant to appear and answer this Complaint;
- C. That this Court adjudge and decree that Defendant has each engaged in the aforementioned acts or practices which violate the Tennessee Consumer Protection Act of 1977;

- D. That, pursuant to Tenn. Code Ann. § 47-18-108(a)(1) and (a)(4), this Court permanently enjoin Defendant, its agents, employees, and all other persons and entities corporate or otherwise in active concert or participation with any of them, from engaging in the aforementioned unfair or deceptive acts or practices which violate the Tennessee Consumer Protection Act of 1977, and that such orders and injunctions be issued without bond pursuant to Tenn. Code Ann. § 47-18-108.
- E. That this Court order Defendant to pay civil penalties of \$1,000 for each and every violation of Tenn. Code Ann. § 47-18-108(b)(4);
- F. That this Court enter judgment against Defendant and in favor of the State for the reasonable costs and expenses of the investigation and prosecution of the Defendant's actions, including attorneys' fees, expert and other witness fees, as provided by Tenn. Code Ann. § 47-18-108(a)(5) and (b)(4);
- G. That all costs in this case be taxed against Defendant pursuant to Tenn. Code Ann.
 § 47-18-116; and
- H. That this Court grant Plaintiff such other and further relief as this Court deems just and proper.

Respectfully submitted,

FOR THE STATE OF TENNESSEE

ROBERT E!COÒPER, JR. Attorney General and Reporter

B.P.R. No. 10934

JENNIFER E. PEACOCK
Assistant Attorney General

B/P/R. No. 22227

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I hereby cartify that this is a true cook of original instrument filed in my office this ______ any of ______ 20 0 3 BICHARD B ROUGER Clock

By _______ Deputs Clock

Deputy Clork